

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/657,373
Filing Date: September 8, 2003
Applicant: Kaiser et al.
Group Art Unit: 3734
Examiner: Kevin T. Truong
Title: SUTURE ANCHOR AND ASSOCIATED METHOD
Attorney Docket: 5490-000361

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 CFR §1.132

I, Kevin Stone, declare as follows:

BACKGROUND

1. I graduated from the University of Dayton in 1987 with a BS degree in Biomedical Engineering. I graduated from Clemson University in 1989 with an MS degree in Biomedical Engineering.

2. I have eighteen years experience in the Biomedical Engineering field.

3. In 2002, I started working for the Biomet Manufacturing Corporation as a development engineer in the Arthrotek division. In 2003 I was promoted to Vice President of Operations, a position I continue to hold to this day. I have

worked in the development of many orthopedic devices, including suture anchors and, I am a named inventor of over 21 patents.

4. I am an inventor of the subject matter claimed in the above-identified patent application.

LONG- FELT UNRESOLVED NEED/FAILURE OF OTHERS

5. Transition from open repair orthopedic procedures to closed repair procedures, including arthroscopic and minimally invasive procedures, has created the need to be able to easily slide and manipulate a suture through the eyelet of suture anchor without easily breaking or fraying the suture.

6. Current eyelet finishes, although generally, adequate have not kept up with the time and reduced space limitations of minimally invasive arthroscopic procedures. Such procedures require quick manipulation of sutures and suture anchors in tight spaces and with often limited visibility. Suture breakage and frictional resistance must be reduced or eliminated.

TESTING AND COMMERCIAL SUCCESS

7. Applying a type II titanium anodize process to the eyelet of a titanium suture anchor increases the fatigue life of the suture by a significant percentage relative to a titanium suture anchor without the titanium anodize process treatment, as shown in the attached table, which summarizes the test parameters and results of tests conducted before filing the application.

8. Commercial production of suture anchors with the titanium anodize

process treatment began in 2003. Today practically all the suture anchors sold by Biomet are provided with the titanium anodize process. Over 30,000 have been sold since January 2003.

9. Further evidence of the commercial success is provided by the fact that there have been no surgeon-reported incidences of suture breakage with use of the treated suture anchors.

10. In my opinion, the commercial success of the claimed invention is a direct result of the titanium anodize finish of the eyelet of the suture anchor, which is not found in other similar products in the market.

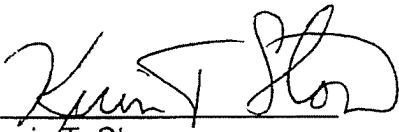
11. I am not aware of titanium anodize process treatment applied to the eyelet of the suture anchor by others before the date of filing this application September 8, 2003.

12. In my opinion, the commercial success demonstrated by the above facts is an indication that the claimed invention attests to the improved uses and performance of the invention and should be relevant as indicia of nonobviousness of the claimed invention over the prior art.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 the United States Code, and that such willful false statement may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is

directed.

Date: 22 Aug 2007


Kevin T. Stone

Titanium Screw Anchor Eyelet		
Finish	Matte	Titanium Anodize Type 2
Suture	#2 Poylester	#2 Poylester
Sterilized	Gamma	Gamma
Load	2.2 LB	2.2 LB
Frequency	1 Hz	1 Hz
Stoke	1 inch	1 inch
Average Cycles	278	498
% Increase	-	79